must be demonstrated that alternate procedures are appropriate and adequate.

The guidance document is available for public examination in the Docket Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Interested persons may, at any time, submit written comments regarding the guidance document to the Dockets Management Branch (address above). Such comments will be considered in determining whether further amendments to, or revisions in, the guidance document are warranted. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. Received comment may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 18, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-19442 Filed 8-25-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88E-0269]

Determination of Regulatory Review Period for Purposes of Patent Extension; Sensor® Model Kelvin® 500 Unipolar Pulse Generator, Model K Endocardial Lead, Model 5000 Transceiver, and Model 50 Lead Tester (Sensor® Model Kelvin® 500)

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for the Sensor® Model Kelvin® 500 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Andrea E. Chamblee, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) generally provides that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under that act, product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 158(g)(3)(B).

FDA recently approved for marketing a medical device known as the Sensor® Model Kelvin® 500 (exercise-responsive cardiac pacemaker) which is indicated for ventricular use in patients with third-degree A-V block, atrial flutter or fibrillation with slow ventricular response, sinus node dysfunction or sick sinus syndrome (including sinus bradycardia, sinus arrest and/or exit block), bradycardia-tachycardia syndrome, and second-degree block Mobritz Type II or trifascicular block. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for the Sensor® Model Kelvin® 500 (U.S. Patent No. 4,543,954) from the Purdue Research Foundation and requested FDA's assistance in determining the patent's eligibility for patent term restoration. FDA, in a letter dated July 25, 1988, advised the Patent and Trademark Office that the medical device had undergone a regulatory review period. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for the Sensor® Model Kelvin® 5—0 is 696 days. Of this time, 572 days occurred during the testing phase of the regulatory review period, while 124 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun:* June 5, 1986. FDA has verified the applicant's claim that the investigational device exemption (IDE G860081) for the device became effective on June 5, 1986.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act:* December 28, 1987. The applicant claims September 4, 1987, as the date of the product marketing application (PMA 870054) for the device became effective. However, FDA records indicate that PMA 870054 was not sufficiently complete to permit substantive review until December 28, 1987.

3. *The date of application was approved:* April 29, 1988. FDA has verified the applicant's claim that PMA 870054 was approved on April 29, 1988.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 412 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 25, 1988, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 21, 1989, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 19, 1988.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 88-19443 Filed 8-25-88; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Policy Development and Research

[Docket No. N-88-1818; FR-2524]

Lead-Based Paint Abatement Demonstration Program

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Announcement of a Lead-Based Paint Abatement Demonstration Program.

SUMMARY: HUD is announcing a demonstration project to test, evaluate, and determine the cost-effectiveness of a number of methods for abating lead-based paint in residential properties. This demonstration project is one element in a broad program of research, development of regulations, and implementation of lead-based paint testing and abatement procedures mandated by section 566 of the Housing and Community Development Act of 1987 (Pub. L. 100-242, approved February 5, 1988 (42 U.S.C. 4822)) (The Act.)

ADDRESS: Organizations interested in being considered as the support contractor or for other related procurements should contact the Office of Procurement and Contracts, ATTN: ACR, Room 5256, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, to be placed on the bidders' mailing lists for such procurements.

FOR FURTHER INFORMATION CONTACT: Ellis G. Goldman, Office of Policy Development and Research, (202) 755-5528, Room 8230, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

Background

HUD last conducted research on issues involving lead-based paint in housing in the 1970's; in the intervening period, continuing research by others on the causes and extent of lead poisoning in children has shown that some abatement methods can actually increase the possibility of lead poisoning. Several new abatement strategies have been suggested and some tested in limited programs; in addition, new materials have been developed for encapsulating paint and for removing existing paint.

As noted, this demonstration project is one element of a larger Departmental research and demonstration program which also includes examination and improvement of lead-based paint testing and detection technology; an estimate of the amount, characteristics, and regional distribution of housing in the United States containing lead-based paint; preparation of a comprehensive and workable plan for the inspection and abatement of privately owned housing; and the development of various technical guidelines to provide direction to future abatement efforts.

Regulatory Status

In 1986 and 1987, HUD revised its regulations on lead-based paint testing and abatement to comply with the decision in *Ashton v. Pierce*, 716 F.2d 56 (DC Cir. 1983), and to reflect advances in knowledge regarding the causes of elevated blood lead levels of children and in hazard detection and abatement techniques. HUD published revised regulations implementing section 566 of the Act on June 6, 1988 (53 FR 20790). Additional regulatory changes will be initiated after HUD conducts this demonstration.

Demonstration Concept

Section 566 requires, no later than 22 months after enactment of the Act, a report to the Congress on the findings and recommendations of a demonstration program of abatement techniques in HUD-owned single and multifamily housing. The demonstration program is to "utilize a sufficient variety of abatement methods in a sufficient number of areas and circumstances to demonstrate their relative cost-effectiveness and their applicability to various types of housing." Section 566 further specifies:

In preparing such report, the Secretary shall examine—

(i) The most reliable technology available for detecting lead-based paint;

(ii) The most efficient and cost-effective methods of abatement;

(iii) Safety considerations in testing;

(iv) The overall accuracy and reliability of laboratory testing of physical samples, X-ray fluorescence machines, and other available testing procedures;

(v) Availability of qualified samplers and testers; and

(vi) An estimate of the amount, characteristics, and regional distribution of housing in the United States that contains lead-based paint hazards at differing levels of contamination.

The demonstration program, in accordance with the requirements of the Act, will be carried out in residential properties held by the Department in the name of the Secretary. The inventory of Secretary-held properties will be reviewed to select properties representative of housing types in various geographic regions suspected of having housing with lead-based paint. The final location of the demonstration projects will be determined on the basis of property availability and program technical requirements which will permit testing of known and promising abatement techniques on a broad range of materials and substrates. It is estimated that the demonstration program will involve approximately 200 housing units. The demonstration program is expected to begin in October 1988 and be completed in December 1989.

HUD will select a demonstration management support contractor through competitive procurement procedures. The support contractor will be expected to assist HUD in planning, managing, and carrying out the lead-based paint detection and abatement activities, and in collecting data on the demonstration program.

The proposed demonstration program will utilize approximately 20 promising methods and materials on approximately 30 substrates. The methods will include paint removal; encapsulation (or covering) of the painted surface; or replacement of the painted material, where costs and effectiveness can be documented and measured. The demonstration program also may involve some abatement methods currently not permitted in HUD's regulations, such as sanding and other abrasive removal methods, provided that appropriate safety measures can be implemented.

Selection of the abatement techniques to be tested and evaluated will be performed by HUD staff and HUD's demonstration management support contractor, with the assistance of information provided by the National Bureau of Standards (NBS) and the National Institute of Building Sciences (NIBS).

Other Information

The Catalog of Federal Domestic Assistance program number is 14.506, General Research and Technology Activity.

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD